

## **NON-TECHNICAL ABSTRACT**

The purpose of this research is to develop a new and powerful type of immune therapy for prostate cancer patients. This therapy involves vaccinations with special stimulator cells found in the human body called dendritic cells. These dendritic cells can take up proteins released from cancer cells and present pieces of these proteins to immune cells called T lymphocytes to create a strong stimulatory signal to fight the cancer.

One of these proteins is called telomerase (hTERT) which is a substance that is found in cancer cells and allows the cancer cells to grow abnormally. In most cancer patients, however, the immune system does not adequately destroy the cancer cells because the T cells are not stimulated sufficiently. In our research, we have found that dendritic cells mixed with telomerase RNA can stimulate the development of immune cells that can recognize and kill cancer cells in the laboratory. In addition, we have shown that a drug called denileukin difitox (ONTAK<sup>®</sup>) may increase this immune response by killing immunosuppressive T cells in the cancer patient.

In order to test this, we have developed a clinical study and will enroll patients with metastatic prostate cancer to receive denileukin difitox (ONTAK<sup>®</sup>) followed by vaccination with telomerase RNA transfected dendritic cells.

The main objectives of this study are to find out whether this form of therapy is:

- a) Safe without inducing any major side effects,
- b) and effective in boosting the patient's body's immunity against telomerase expressing prostate cancer cells.

Finally, we will test whether or not tumor shrinkage based on serum PSA levels or on X-ray studies will occur. We hope that this new form of immune therapy will ultimately slow down tumor growth and prolong survival of prostate cancer patients.